B1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,632	03/06/2002	Clark Lum	HSCI-101	4926

7590 11/29/2004

Michelle S. Marks
Shaw Pittman LLP
1650 Tysons Boulevard
McLean, VA 22102

EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,632	LUM, CLARK	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed March 6, 2002, claims benefit to provisional application 60/276,476, filed March 19, 2001.

Applicant's amendment filed August 27 2004 has been received and entered. Claim 17 has been added. Claims 1-17 are pending and currently under examination.

Election/Restrictions

Applicant's election of the species of CD34+ cells and the HLA-A loci in the reply filed on August 27, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Upon review of the claims, the specification and the art, the species election between the different HLA loci is withdrawn because it would not be an undue burden to consider all the species together. Further, it is found that cord blood and bone marrow are sources for CD34 cells, therefore these two species will be examined together in the instant action. However, the restriction of other different cell types and sources is maintained.

Claims 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species of a CFU-GM cell type, there being no allowable generic or linking claim. Claims 1, 2, 6, 8-12, 14-16 generic to all species of HLA and CD34 and claims 1-6, 8-17 are under examination to the extent the encompass a stem cell manufacturing system of these species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 7-17 are rejected under 35 U.S.C. 102(b) as being anticipated by the New York Blood Center.

The New York blood center was established almost 40 years ago as a center to accept and process blood products. As part of their service and on-going research the NYBC maintains an inventory of frozen blood, marrow and cord blood (as of 1992-as evidenced by Carolinas Cord Blood Bank web site) which each contain CD34 stem cells. The NYBC is a registered member of the National Marrow Donor Registry in which their different supplies of marrow is cataloged by HLA and other determinants important for determining the appropriateness for transplantation into a patient. The NYBC is the largest independent distribution organization in the country serving more than 200 hospitals (see information on quick facts about NYBC). To serve as such a facility, it is fully licensed to meet the requirements of the NY state and the regulations of the FDA.

Claims 1-6, 7-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Carolina Cord Blood Bank.

The Carolina Cord Blood Bank opened January of 1998 and includes the hospitals of Duke, Durham Regional, UNC and Western Wake. The hospitals serve to accept and process

blood products, in particular cord blood from new born babies, which are finally banked at Duke. Cord blood The Carolinas Cord Blood Bank is a registered member of the National Marrow Donor Registry in which their supply of marrow is cataloged by HLA and other determinants important for determining the appropriateness for transplantation into a patient. To serve as such a facility, it is fully licensed to meet the requirements of the North Carolina state and the regulations of the FDA.

Claims 1, 2, 5, 6, 9-13, 16 and 17are rejected under 35 U.S.C. 102(b) as being anticipated by UPS.

The claims are very broad simply encompassing any manufacturing system of stem cells and a delivery system. A manufacturing system broadly encompasses a human because they serve as a source and produce blood and bone marrow. Further, the claims simply requires the delivery system receive and order and be licensed. UPS is a licensed delivery company that was established in 1907. UPS is a company comprised of thousands of workers which all serve as a source of stem cells which are continually expanded. These workers are 'coupled' to the company by virtue of their employment by UPS. Any single worker must comprise at least one of the various HLA loci recited in the claims.

Conclusion

No claim is allowed.

As evidenced by the cited art and those present in Applicants IDS, registered registries and storage banks for bone marrow were known well before the filing date of the instant

application. Further, cord blood banks were established prior to the effective filing date of the instant application. The art teaches that both sources of CD34 hematopoietic stem cells were successfully used in transplantation into patients, and the methodology for typing, culturing and maintaining these cell sources were well known in the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
AU1632